

Applicant : David R. Hennings et al.
Appl. No. : 10/699,212
Examiner : David M. Shay
Docket No. : 15487.4002 (Formerly NSL-501)

IN THE SPECIFICATION:

On page 4, lines 2-13, please replace with the following paragraph:

Most prior techniques to treat varicose veins have attempted to heat the vessel by targeting the hemoglobin in the blood and then having the heat transfer to the vessel wall. Lasers emitting wavelengths of 500 to 1100 nm have been used for this purpose from both inside the vessel and through the skin. Attempts have been made to optimize the laser energy absorption by utilizing local absorption peaks of hemoglobin at 810, 940, 980 and 1064 nm. RF technology has been used to try to heat the vessel wall directly but this technique requires expensive and complicated catheters to deliver electrical energy in direct contact with the vessel wall. Other lasers at 810 nm and 1,06 um have been used in attempts to penetrate the skin and heat the vessel but they also have the disadvantage of substantial hemoglobin absorption which limits the efficiency of heat transfer to the vessel wall, or in the cases where the vessel is drained of blood prior to treatment of excessive transmission through the wall and damage to surrounding tissue. All of these prior techniques result in poor efficiency in heating the collagen in the wall and destroying the endothelial cells.

On page 4, lines 15-16, please replace with the following paragraph:

Baumgardner Patent No. 5,820,626 and Anderson Patent No. 5,810,801 teach the advantages of using the mid IR region of optical spectrum 1.2 to 1.8 um, to heat and shrink collagen in the dermis.

On page 5, lines 5-7, please replace with the following paragraph:

Finally, the methods and apparatus taught in the prior art does not mention the use of diffusing ~~defusing~~ catheter tips for varicose vein treatment. Use of common, standard, non-diffusing

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tip fiber optic and other laser delivery devices increases the risk for perforation of the cannulated vessel.

On page 5, lines 9-16, please replace with the following paragraph:

Navarro et al., U.S. Pat. No. 6,398,777 issued Jun. 4, 2002, teaches a device and method of treating varicose veins that involves using a laser whose wavelength is 500 to 1100 nm and is poorly absorbed by the vessel wall. Laser energy of wavelengths from 500 to 1100 nm will penetrate 10 to 100 mm in tissue unless stopped by an absorbing chromophore. See figure 10X. Most of the energy used by this method passes through the vessel wall and causes damage to surrounding tissue. Procedures using these wavelengths can require cooling of the surface of the leg to prevent burning caused by transmitted energy. Operative complications of this technique include bruising and extensive pain caused by transmitted energy and damage to surrounding tissue.

On page 5, lines 18-21, please replace with the following paragraph:

However, this technique does appear to be clinically effective because the blood that remains in the vein after compression absorbs the 500 to 1100 nm energy. 500 to 1100 nm light is absorbed in less than 1 mm in the presence of hemoglobin. See figure 10X. This blood heats up and damages the vein wall by conduction, not by direct wall absorption as claimed by Navarro.

On page 6, line 24 through page 7, line 5, please replace with the following paragraph:

RF energy can be delivered through a specially designed endovenous electrode with microprocessor control to accomplish controlled heating of the vessel wall, causing vein shrinkage

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or occlusion by contraction of venous wall collagen. Heating is limited to 85 degrees Celsius avoiding boiling, vaporization and carbonization of tissues. In addition, heating the endothelial wall to 85 degrees Celsius results in heating the vein media to approximately 65 degrees Celsius which has been demonstrated to contract collagen. Electrode mediated RFE vessel wall ablation is a self-limiting process. As coagulation of tissue occurs, there is a marked decrease in impedance that limits heat generation.

On page 8, lines 6-15, please replace with the following paragraph:

Patients treated with EVLT have shown an increase in post-treatment purpura and tenderness. Most patients do not return to complete functional normality for 2-3a days as opposed to the 1 day "down-time" with RF Closure.TM.b of the GSV. Since the anesthetic and access techniques for the 2 procedures are identical, it is believed that non-specific perivascular thermal damage is the probable cause for this increased tenderness. In addition, recent studies suggest that pulsed laser treatment with its increased risk for vein perforation may be responsible for the increase symptoms with EVLT vs. RF treatment. Slow uncontrolled pull-back of the catheter is likely one cause for overheating and perforation of the vessel wall as even the best surgeon may have difficulty retracting the fiber at exactly the correct speed to maintain a vessel wall heating temperature of 85 deg C. This technique prevents damage to surrounding tissue and perforation of the vessel.

On page 13, line 23 through page 14, line 5, please replace with the following paragraph:

FIG. 2A is a representative view of varicose veins 200 to be treated according to the preferred embodiment of the method and apparatus of the present invention. FIG. 2B is a

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representative-view of the GSV 202 to be treated according to the preferred embodiment of the method and apparatus of the present invention. FIG. 3A is a representative view showing the beginning of the introducer or dilator 300 for percutaneous access according to the preferred embodiment of the method and apparatus of the present invention. FIG. 3B is a representative view showing the use of the introducer or dilator 300 with the laser fiber 306 having tip 308 passing through the lumen 302 of the dilator 300 and into the GSV 202 according to the preferred embodiment of the method and apparatus of the present invention.

On page 14, insert the following paragraph before line 15 as follows:

FIG. 5 shows manual compression being applied to the patient's leg near laser tip 308.

FIG. 6 shows the use of a thermal sensor device 600 having a sensor 608 together with a cooling system 602 including nozzle 606 which dispenses cooling fluid 604.

On page 15, lines 15-24, please replace with the following paragraph:

Optical absorption curves presented by Baumgardner, Anderson, and Grove Patent No. 5,707,403 show that the primary absorbing chromophore in a vein for the 810, 940 and 1.06 um laser wavelengths is hemoglobin. When a vein is drained of blood and these lasers ~~402~~ are used, a great majority of the laser energy is transmitted through the vessel wall and heats surrounding tissue ~~702~~. The 1.2 to 1.8 um laser wavelengths are ideally suited to penetrate the small amount of remaining blood in the vessel 200 but also is much more strongly absorbed in the vessel wall 704 by collagen. Most of the energy is concentrated in the wall 704 for heating and shrinkage and is not transmitted through to surrounding tissue 702. This dramatically increases, the safety of the procedure. In

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addition these laser wavelength are considered more "eye" safe than the 800 to 1.06 um lasers, decreasing the risk of eye damage to the doctor and others in the operating arena.

On page 17, lines 1-10, please replace with the following paragraph:

Another type of thermal feedback device 600 can be an external device that measures the heat that is transmitted out of the side of the vein 200 or 202 and heats up the surface of the skin 608 adjacent the treated vein 200 or 202. As described above, this detector can be either a contact thermocouple or a, non contact infrared detector 600. A particularly advantageous use of this type of thermal detection would be to automatically activate a cooling device 602, such as a cryogen spray 604, onto the skin surface 604 to keep it cool, or to send an alarm signal to the operator of the laser that too much energy is being delivered to and escaping from the treatment site. In an optional configuration, the laser operator could point an external detector at a red aiming light that is visible through the skin from the end of the treatment, fiber, similar to the use of the ultrasound device currently used, in order to control the location and duration of the delivery of the laser energy.

On page 17, line 12 through page 18, line 2, please replace with the following paragraph:

FIG. 6 is a representative view of the non-contact thermal sensor 600 and the cooling system 602 of the preferred embodiment of the method and apparatus of the present invention. Non-contact thermal sensors 600 as well as contact devices, including RTDs, are well known in the art. It will be understood that the cooling device 602 can be any suitable, controlled device which allows a predetermined amount of cryogenic fluid to be dispensed from an on-board fluid reservoir or from an external/line source. In a preferred embodiment, the device 602 is computer controlled, to provide

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spurts or squirts of cryogenic fluid at a predetermined rate or for a predetermined duration. The cryogenic fluid 604 is dispensed onto the surface of the skin ~~604~~ in an area adjacent the fluid dispensing nozzle 606, and the non-contact thermal sensor 600 determines the temperature of the skin in the same area 604 or in an area 608 distal from the area being cooled 604. The present invention, this application and any issued patent based hereon incorporates by reference the following issued patents with regards surface cooling methods and apparatus utilized in the present invention: U.S. patent application Ser. No. 08/692,929 filed Jul. 30, 1996, now U.S. Pat. No. 5,820,626. U.S. patent application Ser. No. 938923 filed Sep. 26, 1997, now U.S. Pat. No. 5,976,123. U.S. patent application Ser. No. 10/185,490 filed Nov. 3, 1998, now U.S. Pat. No. 6,413,253. U.S. patent application Ser. No. 09/364275 filed Jul. 29, 1999, now U.S. Pat. No. 6,451,007.